# Symphonie Aqua System VC

Gebrauchsanleitung | Instructions for use


# GEBRAUCHSANLEITUNG

## INSTRUCTIONS FOR USE



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# INSTRUCTIONS FOR USE ENG

Dear Symphonie Aqua User,

Thank you for choosing the Symphonie Aqua System.
This innovative impression system was developed and produced for orthopaedic technology. The quality products from Romedis undergo extensive quality assurance and documentation, as well as close-meshed tests in order to ensure flawless production.


**max. 0,3 bar / cylinder**

# 1. Safety Instructions and Precautionary Measures

Please read the instructions carefully before initial operation and carefully store them for future accessibility.

The Symphonie Aqua System VC TF was developed exclusively for orthopaedic technology. It is solely intended for creating prosthetic impressions of the lower extremities, following transfemoral amputation. (For knee disarticulation, the Aqua Pad is applied.)

Application for other purposes has not been approved. The approved, maximal girth of the femoral residual limb for the Symphonie Aqua System VC TF is 78cm. The approved, maximal bodyweight for the Symphonie Aqua System VC TF is 170kg.

The user is responsible for the proper application and utilisation of the device as well as accidents and dangers which occur to people or property.

Please hand this device over only to those who are familiar with qualified application.

Before using, check the device for damages and operational capability.

Use only spare parts or original components for the Symphonie Aqua System VC TF which come from the Romedis GmbH.

Do not use any caustic or acidic cleaners!

A membrane replacement is recommended after 12 months.

Products from the Romedis GmbH are constantly being further enhanced. We reserve the right to change form, technology and configuration.

Therefore, no claims can be made that are derived from the descriptions and illustrations in these instructions.

Please adhere to country-specific standards and regulations. In these instructions you receive important information regarding the correct usage, initial operation, maintenance and cleaning of the Symphonie Aqua System VC TF.

Do not open the control unit. If you open the control unit the warranty of the device will automatically expired.

There is a highly risk of injury!

If any problems occur, please contact our customer service.

**OPERATING INSTRUCTIONS**

- Read the instruction carefully.
- **Make sure that the membrane is clean. No plaster residue!**
- When not in use, units should be filled for storage. No pressure!
- Use sufficient amount of casting lube.
- Pull protective bag over the plaster bandage.
- Calculate the recommended pressure with the VC App.
- Clean the membrane after each use. Don´t use a pointed item for cleaning!

## 2. Important Components

**The Symphonie Aqua System VC consists of:**

1. Hose connector (letter 1), water intake
2. Attachement or hose (letter 2), general hose mounting
3. Hose Connector (letter 3), water drain
   Secure the open end of the hose in the sink to avoid damage by water
4. Connection for compressed-air hose **max. 6 bar**
   (use only clean compressed air which is not charged with oil)
5. Symphonie Aqua VC Steuerungskasten
6. Symphonie Aqua System Inlet hose to VC box
7. Silicone membrane
8. Pressure manometer **max. 0,3 bar**
9. Stopcock
10. Foot pedal for the VC TF cylinder
11. Venting screw
12. Centring aid

1 - 4 Connecting Hoses


12. Connect hose from Symphonie Aqua cylinder to attachment No. 1 on foot pedal

13. Connect inlet hose 1 from the water tap to attachment No. 2 on foot pedal

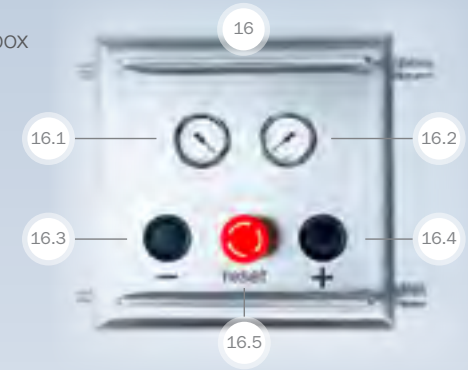


14. Height adjusting discs
14.1 4 sized S (3 cm)
14.2 2 sized L (6 cm)
14.3 TF hemisphere

15. Solid cup with distal bearing cushion
15.1 10 cm diameter, height 8 cm
15.2 12 cm diameter, height 8 cm
15.3 14 cm diameter, height 8 cm
15.4 16 cm diameter, height 8 cm




16. Symphonie Aqua VC control unit box
16.1 Pressure in cylinder
16.2 Negative pressure manometer
Pressure in control unit box
16.3 – button for decompression
16.4 + button for increase of pressure
16.5 Reset button, red button




## 3. Labelling of the device

Venting
Only for venting after filling, according to instructions.
The serial number of the cylinder is on the underside of the device.
The serial number of the VC unit control box can be found on the underside of the device.
Please keep ready in case it is needed.

## 4. Required Material

- When filling, use only cold tap water without additives.
- Plaster dressing
- Casting Bags (Gipstüten SA 146 1)
- Have sufficient amount of Casting Lube at hand (SA 144 1)
- 1 thin nylon stocking
- Bucket of plaster with cold water
- Cling film

## 5. Preparation

When delivered, all system components are fully assembled and inspected for impermeability.

Before operating the system, connect the VC TF cylinder / unit control box with the 4 hoses.

Fill by using the foot pedal; let the escaping air out by using the minus button and the drain hose. (Important: filling with water by using the foot pedal takes place very quickly. Therefore, always have an eye on the cylinder manometer. Maximum pressure of the TF cylinder is 300 mbar.)

Connect the water inlet hose to the pressure container on the foot pedal.

From there, the hose attached to the cylinder is connected to the foot pedal.

(The VC control box is not needed for filling the cylinder.

The maximal pressure is 300 mbar. Pay attention to the manometer on the cylinder – danger of excess pressure!) (Fig.1).

Fig. 1

Connect the hose (2) for drainage from pressure container to the coupling on the VC control unit box (Fig. 2) and attach this to the pressure container (Fig. 3).

Fig. 2

Fig. 3

Connect the hose (3) for drainage from the coupling on the VC control unit box (Fig. 4) and attach this to the water drain (Fig. 5).

Fig. 4

Fig. 5

Connect finally, the compressed air hose - max. 6 bar (not included in shipment) (Fig. 6).

Fig. 6

During the impression process, all hoses remain connected to the system.

Lay the cylinder at a slant, so that the venting screw points upward, in order to be sure of a complete venting (Fig. 7).

Fig. 7

Remove the venting screw and then open the stopcock (Fig. 8).

Fig. 8

Open the water-tap (fill with cold water). Slowly start filling the cylinder with water, using the foot pedal (pressure increase.)

Important: Be sure to completely fill with water, without air bubbles.

One knows that this is achieved when water runs out of the vent hole in this position (Fig. 9).

Fig. 9

Optionally, you can sufficiently vent the cylinder by using the "– button" on the VC control unit. Tilt the cylinder so that its highest point is the drainage hose.

Fill by using the foot pedal; let the escaping air out by using the minus button and the drain hose.

(Important: filling with water by using the foot pedal takes place very quickly. Always keep an eye on the cylinder manometer. Maximum pressure of the TF cylinder is 300 mbar.) After filling, be aware of the increased weight of the cylinder (approximately 30 kg).

After the container has been filled:

· Close the venting screw

· Carefully place the cylinder on the floor in an upright position (vestibule opening facing upward).

Protect the connections and components from damage and impact.

Only use the device when completely assembled.

The system is now ready for use (Fig. 10).

Fig. 10

## 6. Application

Safety instruction:
Do not leave your immediate location during the plaster impression!

**Clean the membrane after every application. Observe the cleaning instructions.**

Do not use any caustic or acidic cleaners!

**In order to obtain a correct impression, you will need:**

· cold water
· plaster dressing
· Casting Lube (article No. SA 144 1)
· 1 nylon stocking
· PVC protective covers
· optional cling film and copying pencil

For socket systems that use a liner for mounting the prosthesis, it may be advantageous to use the corresponding liner for making the impression.

If necessary, use a thin film (e.g. cling film) to protect the textile outer fibre of the liner (Fig. 11).

Fig. 11

For pins (Shuttle Lock Treatment), always remove the pin (danger to the membrane).

Please make sure that the silicone membrane is in sound condition before each use.

Check that the patient, as well as the cylinder, are standing securely. If needed, provide a handhold. As an option, you can purchase the Symphonie Aqua Lifter.

Position the cylinder at the appropriate height, so that an optimal plaster casting result can be obtained.

Before use, the cylinder height must be aligned to the patient.

The recommended pressure for transfemoral and knee disarticulation patients lies between 230 and 260 mbar.

Choose the solid cup according to the size of the distal end of the residual limb (Fig. 12).

Abb. 12

The residual limb must not come in contact with the rim of the solid cup (danger of deformation).

If a solid cup that is too large is chosen, there is too much space between the residual limb and membrane.

Choose the size of the distal end bearing cushion that fits the solid cup.

Recheck your choice for the patient. Next, determine the correct height in the system and then measure the length from the distal end of the residual limb to the desired socket height (pubic bone, perineum) and calculate the difference in regard to the entire length of the height-compensating discs, always beginning with the distal end cap (Fig. 13).


Fig. 13

**To calculate the height of the vector tower, proceed as follows:**

**1.** Residual limb length from pubic bone to distal limb end, e.g. 25 cm.

**2.** Membrane base in cylinder to upper edge of membrane in filled state is 51 cm.

**3.** Important: In order to achieve an optimal shape construction in the groin, the membrane is held up by silicon positioners.

**4.** The calculation is as follows:
Maximal Aqua System depth 51 cm
Residual limb length, e.g. 25 cm

51cm - 25cm = 26cm VTH

26 cm VTH (vector tower height) (VTH consists of distal TF hemisphere 10 cm, and the appropriate formed cup.)

Assemble correctly; be sure to choose the right girth! For shorter residual limbs, include the appropriate spacer

discs in the screwing process. When choosing the size of the formed cup, be sure that the distal residual limb end fits completely into the cup. However, do not choose a size that is too big.

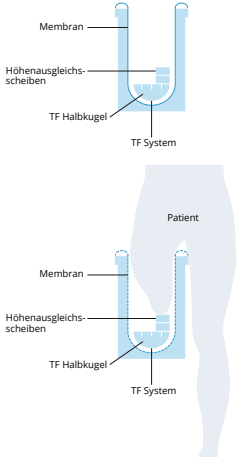
Screw the TF hemisphere, the height-compensating discs and the solid cup (including foam cushion) together (Fig.14).

Fig. 14

The TF hemisphere was especially developed for the Symphonie Aqua VC TF system. The hemisphere has several connecting points with which one can connect the height-compensating discs. One is much better able to respond to

- abduction
- adduction
- extension
- flection

of the residual limb during the casting process in the cylinder.




In order to place the vector tower into the system, empty the water completely from the cylinder, using the reset button (Fig. 15).


Fig. 15

Carefully sink the completed, screwed vector tower into the middle of the cylinder. For this, use the grip straps in the cup. Now, place the distal bearing cushion back in (Fig. 16).


Fig. 16

The new Symphonie Aqua Centering Aid was especially developed for the Symphonie Aqua VC TF system and serves as an additional space filler for very small and thin residual limbs.
The centring aid is placed after the cast insulating creme has been applied, and before the casting process in the cylinder takes place. Roll in the centring aid and lay it carefully and horizontally in the TF cylinder. The widest area of the centring aid should always be placed laterally on the residual limb.

Please take note: the centring aid is appropriate for very small and thin residual limbs, with a girth of less than 57cm. Therefore, it is not necessarily required for all residual limbs. (Fig. 17)


Fig. 17

Fill the system up to the residual limb end bearing cushion with water, by pressing the foot switch to save space (Fig. 18).


Fig. 18

To avoid membrane adhesion, lubricate the membrane above the distal bearing cushion with cast insulating creme (Fig. 19).


Fig. 19

During the affixing of the plaster dressing, the patient remains seated!
In order to wrap the plaster dressing onto the liner without bubbles, we recommend pulling a thin film over the nylon stocking (Fig. 20).


Fig. 20

Wrap the residual limb with wet plaster dressing, alternating between clockwise and counter-clockwise directions.
Wrap the entire residual limb.
Wrap without pressure! (Fig. 21)


Fig. 21

The number of layers should be oriented to the general dimensions and thickness of the residual limb. To avoid damage, please do not wrap too thinly.

Be sure to close the distal end. Afterwards, coat the plaster smoothly. If needed, mark problematic structures as well as the patella or the frontal side in order to be better oriented with the impression.

Tip: Use cold water to avoid an early hardening of the plaster (Fig. 21).

In order to protect the system from impurity, pull a film over the fresh plaster. (Fig. 22)


Abb. 22

Make sure that the patient is able to bear the load of the amputated side (while standing) for the duration of the impression.

In a standing position, the patient can now place his/her residual limb in the middle of the cylinder opening, so that there is light contact with the distal bearing cushion. Sinking too deeply would seriously impair pressure distribution on the residual limb.

Practical tip:
For pear-shaped residual limbs, also place cut-out assistance in, so that the plaster Impression can be removed again. Make sure that the residual limb completely sinks to the height of the desired proximal socket edge in the cylinder (observe linear measure of the system depth).

For extreme back tapering, it may be necessary to cut open the impression. (Fig. 23)


Abb. 23

The pressure container is now filled further, until the patient feels a slight pressure.

At about 200mbar, be sure that the patient's residual limb now statically bears the load completely, or as well as possible. Fill the cylinder (using the foot pedal) to the desired pressure.
During the impression process, pressure should be kept constant. Observe the condition of the patient.

Practical tip:
Using the SAS VC TF System, longitudinal oval socket forms (ischial) as well as sub-ischial socket forms can be made.
For a socket form that contains the pubic bone, the technician should lay a hand between the pubic protuberance and the membrane before the pressure is reached.
This makes taking an effortless impression of the bony anatomical structure possible.



For sub-ischial sockets, the compression pressure of the water on the connective tissue is enough.
For safety reasons, prepare a handhold (e.g. using the Symphonie Aqua Lifter).
Due to the corresponding water pressure, the pressure on the residual limb will be completely evenly distributed.
It is especially advantageous that the resulting shifting of soft tissues (which are normally burdened) already takes place during the plaster impression.
Depending on the type of the plaster dressings applied, the standard setting time is spent in a completely burdened and static state.
During the setting time, the patient can give you valuable information regarding socket volume and bony structures of the stump.
This facilitates the modifying of the plaster cast, due to the bodyweight and water pressure on the residual limb (Check circumference!).

After the plaster dressing has hardened, the patient reduces the load on the amputated side (Fig. 24).


Abb. 24

Using the „– button", let out water to reduce pressure in the system. The remaining water is then pumped out of the system by using the „reset" button.

Important:
In order to avoid sinking deeper into the distal bearing cushion, the patient slowly pulls the residual limb out of the system, as the water pressure decreases.

Next, remove the film, after which the plaster impression is removed, by slowly pulling it from the residual limb (Fig. 25).


Abb. 25

Drain the system completely and remove the vector tower, with the aid of retaining straps.

Possible plaster residue in the system must be removed completely to avoid any damage to the membrane.

Begin the process of producing a test socket.

## 7. Symphonie VC-App

Symphonie VC is an orthopaedic app from the Romedis GmbH which is free of charge. It assists the orthopaedic technician in calculating the recommended pressure when providing prosthetic care, using the Symphonie Aqua System VC.

How a prosthesis fits depends primarily on the form of the socket. Control, wearing comfort and adhesion are determined by the plaster impression.

The Symphonie Aqua System makes it possible, for the first time, to determine the stump's burden within the prosthetic socket under actual conditions. Due to the resulting hydrostatic pressure, individual tissue states are revealed and can be exactly determined in the socket.

Soft tissue, bony structures or scar tissue are detected. In order to achieve a proper socket fit during the first impression, the hydrostatic pressure must be regulated for each patient when using the Symphonie Aqua System VC.

The orthopaedic technician can calculate the recommended pressure from the VC app by means of the following parameter:

- the patient's weight in kilograms
- the circumference of the stump at the MPT (mid patella tendon) in centimeter
- the firmness of the tissue (soft, middle or hard)
- the athleticism of the patient, ranging from 1 (unathletic) to 4 (athletic).

The prevailing pressure can be adapted to the recommended pressure during the treatment, with the help of the control unit.

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## 8. Tips for Maintenance and Care

The guarantee of the mebran is nine months.

Clean the membrane after each usage. Follow cleaning instructions! Do not use a cleanser for cleaning the membrane. Cleanse only with water and a soft cloth. Keep the System from extreme temperatures. Do not use a high-pressure cleaner.

Do not attempt to modify the device. It is only to be used for intended purposes. Misuse can result in damage to the unit and or personal/patient injury.

For injury to persons and damages to materials occuring from improper usage, the Romedis GmbH excludes any liability.

The device is solely approved for orthopaedic technology and the production of plaster impressions of the lower extremities, following transfemoral amputation.

## 9. Storage and Transport

During transport and storage, be careful of the connections and hoses.

Do not hit, crush or place near (or into contact with) sharp objects.

Protect the compensation tank from damage. Keep the device from impact and from turning over. Protect the membrane from caustic materials, sharp or pointed objects. Before using, check that it is in safe, operating condition.

Protect the membrane from extreme hot and cold temperatures!

Please contact the distributor or manufacturer concerning repairs or damages.

If you have questions regarding the Symphonie Aqua System VC, you can reach us by telephone at
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E-Mail at: info@romedis.com

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